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08/912,951

APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
08/912,951	08/14/97	CECH	1
			15389-002606
			EXAMINER

HM21/0929

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ART UNIT	PAPER NUMBER
1642	9

DATE MAILED: 09/29/98

This is a communication from the examiner in charge of your application.  
COMMISSIONER OF PATENTS AND TRADEMARKS

#### OFFICE ACTION SUMMARY

☒ Responsive to preliminary amendments filed on 3/2/98 & 2/23/98

☐ This action is FINAL.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

#### Disposition of Claims

- ☒ Claim(s) 24-35 and 46-82 is/are pending in the application.  
Of the above, claim(s) 24-35 is/are withdrawn from consideration.  
☐ Claim(s) \_\_\_\_\_ is/are allowed.  
☒ Claim(s) 46-82 is/are rejected.  
☐ Claim(s) \_\_\_\_\_ is/are objected to.  
☐ Claim(s) \_\_\_\_\_ are subject to restriction or election requirement.

#### Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.  
☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.  
☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.  
☐ The specification is objected to by the Examiner.  
☐ The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. § 119

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).  
☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been  
☐ received.  
☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_  
☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

- ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

#### Attachment(s)

- ☐ Notice of Reference Cited, PTO-892  
☒ Information Disclosure Statement(s), PTO-1449; Paper No(s) 7 sheets  
☐ Interview Summary, PTO-413  
☐ Notice of Draftsperson's Patent Drawing Review, PTO-948  
☐ Notice of Informal Patent Application, PTO-152

-SEE OFFICE ACTION ON THE FOLLOWING PAGES-

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### **DETAILED ACTION**

Claims 1-45 were originally filed in the application. Claims 1-23 and 36-45 were canceled, and claims 46-82 were entered by the preliminary amendment filed March 2, 1998. Claims 24-35 and 46-82 are pending in the application.

### ***Election/Restriction***

Applicant's election without traverse of Group III, claims is acknowledged. Claims 24-35 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

### ***Drawings***

The drawings are considered to be informal because they fail to comply with 37 CFR 1.84(a)(1) which requires black and white drawings using India ink or its equivalent.

**Color drawings** are acceptable only for examination purposes unless a petition filed under 37 CFR 1.84(a)(2) or (b)(1) is granted permitting their use as formal drawings. In the event applicant wishes to use the drawings currently on file as formal drawings, a petition must be filed for acceptance of the **color drawings** as formal drawings. Any such petition must be accompanied by the appropriate fee as set forth in 37 CFR 1.17(I), three sets of drawings and an amendment to the first paragraph of the brief description of the drawings section of the specification which states:

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The file of this patent contains at least one drawing executed in color. Copies of this patent with color drawing(s) will be provided by the Patent and Trademark Office upon request and payment of the necessary fee.

Color photographs will be accepted if the conditions for accepting color drawings have been satisfied.

***Claim Rejections - 35 USC § 112, second paragraph***

Claims 59, 71 and 82 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The first occurrence of the word "protein" should be deleted from claim 59.

Claim 71 is vague and indefinite in the term "non-naturally occurring" - non-naturally occurring in the host cell or in any cell?

Claim 82 depends from a non-elected claim.

***Double Patenting***

Claims 46-82 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 23-28 and 37 of copending Application No. 08/854,050. Although the conflicting claims differ somewhat in scope, they have a great deal of overlapping subject matter and thus, are not patentably distinct from each other. Instant claim 46-82 are directed to cells containing recombinant polynucleotides encoding hTRT

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polypeptides. Claims 23, 24 and 28 of 08/854,050 are directed to isolated, synthetic, substantially pure or recombinant polynucleotides encoding human telomerase reverse transcriptases (hTERTs) or fragments thereof. Claim 25 of 08/854,050 requires that the polynucleotides be operably linked to a promoter sequence. Claims 26 and 27 of 08/854,050 are directed to cells containing these recombinant polynucleotides. Claim 37 of 08/854,050 is directed to compositions containing polynucleotides encoding hTERT polypeptides.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

### ***Allowable Subject Matter***

The prior art neither teaches nor suggests the instant cells comprising nucleotides encoding human telomerase reverse transcriptase polypeptides. Claims 46-82 are free of the prior art and would be allowable upon the submission of a properly executed terminal disclaimer, and,

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for claims 59, 71 and 82, if amended to overcome the rejection under 35 U.S.C. 112, second paragraph.

*Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Toni R. Scheiner whose telephone number is (703) 308-3983. The examiner can normally be reached Monday-Friday from 8:30 to 5:00.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

9/27/98

*Toni R. Scheiner*

TONI R. SCHEINER  
PRIMARY EXAMINER  
GROUP 1800